

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

2552. Misbranding of penicillin-G sodium crystalline. U. S. v. 88 Vials * * * .
(F. D. C. No. 25508. Sample No. 9439-K.)

LIBEL FILED: September 1, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about March 8, 1948, from Newark, N. J., by the Vitamin Corporation of America.

PRODUCT: 88 100,000-unit vials of *penicillin-G sodium crystalline* at New York, N. Y.

LABEL, IN PART: "Penicillin-G Sodium Crystalline * * * Manufactured for Solvecillin, Inc. * * * Newark, New Jersey."

NATURE OF CHARGE: Misbranding, Section 502 (1), the article was represented as a drug composed wholly of penicillin-G sodium crystalline, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued as provided for by Section 507; and, Section 502 (a), the label statement "Lot No. 3127C Exp. Date Nov. 1950" was false and misleading since the statement represented and suggested that the article had been certified by the Federal Security Administrator under such identifying terms, whereas, it had not been so certified.

DISPOSITION: September 23, 1948. Default decree of condemnation. The product was ordered delivered to a charitable organization.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2553. Action to enjoin and restrain the interstate shipment of Paracelsus. U. S. v. American Biochemical Corporation. Injunction granted. (Inj. No. 203.)

COMPLAINT FILED: On or about November 18, 1948, Northern District of Ohio, against the American Biochemical Corp., Cleveland, Ohio.

ALLEGED VIOLATION: The complaint alleged that the defendant had been and was continuing to ship in interstate commerce a product known as *Paracelsus*, which consisted essentially of a mixture of chemical salts and which was distributed for use both as a dietary food supplement and for therapeutic purposes.

That accompanying the product there was and had been theretofore printed and graphic matter relating to the product entitled "Malnutrition, Disease, Due to Mineral Lack," which described the product and related to it; that the printed and graphic matter had been shipped by the defendant into interstate commerce and had been used with the product by the consignees and had been associated together with the product.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling were false and misleading. These statements represented and suggested that the article was effective to prevent and cure malnutrition and disease, to provide pep, to stimulate hormone production, and to prevent and cure arthritis; and that all individuals suffer from mineral deficiency and would benefit by use of the article. The article was not effective for such purposes and was not capable of fulfilling the promises of benefit

*See also No. 2596.